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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/531,546

10/21/2005

William R. Freeman

00015-017001/SD2001-200-1

3894

26138

7590

09/28/2010

Joseph R. Baker, APC

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4660 La Jolla Village Drive, Suite 750

San Diego, CA 92122

EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

09/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/531,546 | Applicant(s) FREEMAN, WILLIAM R. | |
| | Examiner GIGI HUANG | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-12,14,16-37 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 19-23,25-37 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-12,14,16-18,24,41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The previous action is vacated and replaced by the action presented below.

Status of Application

1. The response filed June 30, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:
 - a. Claims 1, 14, 24 have been amended.
 - b. Claim 2-3, 15 has been cancelled.
2. Claims 1, 4-12, 14, 16-37, 40-42 are pending in the case.
3. Claims 1, 4-12, 14, 16-18, 24, 41-42 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.
6. New grounds of rejection are set forth in the current office action.
7. In a conversation with Joseph Baker on September 16, 2010, the issue of the reference to Jampol as not being prior art in the arguments is clarified. Joseph Baker addressed that the statement was directed to the affidavit in 1/4/2010, where the current amendments to the claims was intended to bring the claimed subject matter within the scope of the evidence for possession prior to Jampol. Review of the claims and affidavit with exhibits, supports that Applicant was in possession of the instant claimed subject matter at least to May 7, 2001 where Jampol is no longer prior art.

New Grounds of Rejection

Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 4-12, 14, 16-18, 24, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strong et al. (U.S. Pat. Publication 2003/0087889) in view of Freeman et al. (Simultaneous Indocyanine Green and Fluorescein Angiography Using a Confocal Scanning Laser Ophthalmoscope).

Strong et al. teaches a method of selection and treatment of patients with occult choroidal neovascular lesions (CNV) including patients with age-related macular degeneration (AMD) with photodynamic therapy (Abstract). Strong et al. teaches that laser photocoagulation is limited to well-demarcated extrafoveal and juxtafoveal CNV and small well-demarcated subfoveal lesions unlike photodynamic therapy (PDT) with verteporfin which can selectively destroy the CNV without significant destruction of the overlying tissue and possibly occluding new vessels with the CNV lesion. Strong teaches assessment of the lesion (e.g. Example 1-2) with a fluorescein angiogram, determination if the lesion spares the foveal center ("not subfoveal", i.e. extrafoveal, juxtafoveal) or in the avascular zone as CNV can occur anywhere in the fundus ([147], Example 2), selecting the treatment, and providing PDT by administering the photosensitizer (verteporfin), allowing time for the photosensitizer to localize in the lesion, followed by light application at a wavelength of 689nm (verteporfin absorption

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spectrum, [8]), and follow up angiography is preferred at least every 3 months with repeated PDT if new leakage is present. The light sources commonly used for these light wavelengths (e.g. 689nm) are non-thermal lasers (coherent light) and LEDs (light emitting diodes, non-coherent light- paragraph 8).

The lesion size and location are determined prior to treatment with baseline measurements that can be determined by fluorescein angiographic photographs and a fundus camera (e.g. Example 2- [131-152]). The photodynamic therapy can be performed with a number of photoactive compounds including hematoporphyrins, texapyrins, and verteporfin (also known as BPD-MA, absorption spectrum 689nm as addressed above) where the absorption spectrum of the compound is typically between 350nm to 12nm, more preferred 400-900nm, and even more preferred 600-900nm (e.g. [44-49]); were mixture of these compounds can be used for the method depending on the absorption of light preferred. The compounds can be delivered in various forms (e.g. liposomal) and administered in several ways including intravenously, orally, and locally [86-90]. The fluence for irradiation of the area can vary widely depending on the depth of tissue, type of tissue, fluid in the area, but the preferred range is from about 20-200J/cm² (paragraph 101), with particular fluences of 50, 75, and 100 J/ cm² taught, and 50J/ cm² exemplified with verteporfin (Example 3 [159-161], claimed) and evaluation with fluorescein angiography (paragraph 162) (see full document, specifically Abstract, [3-4, 7-8, 10-12, 14-24, 27-28, 40, 44-85, 85-96, 101-113, 131-152, 159-162], claims).

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Strong et al. does not expressly teach the use of a high speed scanning laser ophthalmoscope (SLO) and indocyanine green as a photoimaging agent, but does teach the use of a fundus camera and angiography with fluorescein (e.g. [142-147]).

Freeman et al. teaches that a compact digital confocal scanning laser ophthalmoscope (high speed SLO) with true simultaneous fluorescein and indocyanine green (ICG) angiography. Freeman teaches that while fluorescein and ICG angiography are both useful in the diagnosis and treatment of many retinal diseases, sometime both tests must be used and utilizing both can be time-consuming and use multiple injections, where their method with the SLO/fluorescein/ICG overcomes these issues and has the advantage of simultaneous angiography with optimal visualization of retinal and subretinal structures in fluorescent digital (near-real time) imaging plus increased convenience and speed (took less time and less injections).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the compact scanning laser ophthalmoscope (SLO) with fluorescein/ICG instead of fundus camera photography and traditional fluorescein angiography , as suggested by Freeman, and produce the instant invention as it is obvious to substitute the photographic imaging/angiograph of the traditional fundus camera and fluorescein angiography, with the (SLO) with fluorescein/ICG as it has substantial advantages such as better quality, greater image detail, and greater convenience (faster, less injections) which are desirable advantages where one would be motivated to substitute this form of imaging over the other.

Response to Arguments

9. Applicant's arguments with respect to Levy in view of Jampol and Roach (and in view of Levy or LumaCare), or Sullivan in view of Jampol and Roach (and in view of Levy or LumaCare or Miller), are moot as Jampol is not longer prior art as addressed above.

Conclusion

10. Claims 1, 4-12, 14, 16-18, 24, 41-42 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, FEREDOUN SAJJADI can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/
Examiner, Art Unit 1617
/Zohreh A Fay/
Primary Examiner, Art Unit 1627